

Application Number 10/008,243  
Responsive to Office Action mailed December 23, 2004

### **REMARKS**

This Amendment is responsive to the Office Action dated December 23, 2004. Applicants have amended claims 1, 3, 8-14, 17, 28, 35, 36, 41, 42 and 53, and canceled claims 2, 4, 5 and 21. Claims 1, 3, 7-20 and 22-59 are now pending.

Applicants respectfully traverse all pending rejections for the reasons previously explained on the record. However, in the interest of advancing prosecution of the application toward issuance, Applicants have amended various claims to more clearly define the inventions and more clearly distinguish the applied prior art. Applicants do not acquiesce to any of the Examiner's rejections and reserve the right to present one or more of the previously rejected claims in a continuation application.

#### **Claim 1**

In this Amendment, Applicants have amended independent claim 1 to recite a device comprising an external defibrillator; a hermetically sealed pouch containing an electrode, wherein the electrode is an external defibrillation electrode for placement on a patient's skin; an anchor that fastens the pouch to the external defibrillator; and a handle that when pulled, causes the handle to move away from the anchor and tear the pouch to provide access to the electrode contained within the pouch. The limitations introduced into claim 1 were formerly recited in claims 2, 4 and 5, and portions of former claim 10.

In the Office Action, the Examiner rejected claims 1 and 7-14 under 35 U.S.C. 102(b) as being anticipated by Costanzo (U.S. Patent No. 3,407,818) (hereafter Costanzo). The current amendment to claim 1 incorporates the features of former dependent claims 2, 4 and 5. Accordingly, the rejection of claim 1 as being anticipated by Costanzo is no longer applicable to the pending claims. Applicants reserve further comment on the Costanzo reference at this time.

In the Office Action, the Examiner rejected claims 1, 7-9 and 11-14 under 35 U.S.C. 102(b) as being anticipated by Belt et al. (U.S. Patent No. 4,420,078) (hereafter Belt). The current amendment to claim 1 incorporates the features of former dependent claims 2, 4 and 5. Accordingly, the rejection of claim 1 as being anticipated by Belt is no longer applicable to the pending claims. Applicants reserve further comment on the Belt reference at this time.

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In the Office Action, the Examiner rejected claims 1-3, 5, 10, 15-20, 28-30, 53 and 55-59 under 35 U.S.C. 102(e) as being anticipated by Janae et al. (U.S. Patent No. 6,675,051) (hereafter Janae). The current amendment to claim 1 incorporates the features of claim 4. Accordingly, the rejection of claim 1 as being anticipated by Janae has been overcome.

Applicants note for the record that while the cover sheet of the Office Action indicated that claim 4 was rejected, the Examiner advanced no substantive rejection to claim 4 in the text of the Office Action. Accordingly, it appears that the Examiner merely objected to claim 4 as being dependent upon a rejected base claim. As claim 4 was not rejected in the Office Action, the incorporation of the features of claim 4 (and other features) into claim 1, should place this claim in condition for immediate allowance.

With regard to the Janae reference, Applicants also note that the Examiner's statement that "Janae et al. clearly show something that serves to hold an object firmly (an anchor), i.e., the polypropylene- or polyethylene- coated metal film on side 42" is a plain misinterpretation of the Janae reference. The polypropylene- or polyethylene- coated metal film described by Janae, are said to provide a suitable moisture barrier to the package, not to anchor the package to a defibrillator, as the Examiner's analysis appears to suggest. Janae simply does not disclose or suggest an electrode pouch anchored to a defibrillator, as required by claim 1. In any case, this point should be moot in view of the amendment to claim 1 and the comments above. Claim 1 and the respective dependent claims should now be in condition for allowance.

#### Claims 17, 28 and 53

In this Amendment, Applicants have amended independent claims 17, 28 and 53 to recite a ring-shaped handle. This limitation formerly appeared in claim 21, which was dependent upon claim 17. Claim 21 has been canceled in view of the amendment to claim 17.

Claim 17 now recites a device comprising a pouch containing a defibrillation electrode, the pouch comprising a ring-shaped handle that when pulled causes the pouch to tear open.

Claim 28 now recites a method comprising sealing a defibrillation electrode in a pouch; and constructing a ring-shaped handle on the pouch that when pulled causes the pouch to tear open.

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Claim 53 now recites a method comprising obtaining a pouch containing a defibrillation electrode hermetically sealed within the pouch; and tearing open the pouch by pulling a ring-shaped handle.

In the Office Action, the Examiner rejected claims 1-3, 5, 10, 15-20, 28-30, 53 and 55-59 under 35 U.S.C. 102(e) as being anticipated by Janae. As the limitation formerly recited in claim 21 is now included in independent claims 17, 28 and 53, this rejection has been overcome.

In the Office Action, the Examiner also rejected claims 17, 18, 28-31, 34, 53, 55 and 56 under 35 U.S.C. 102(b) as being anticipated by Walters et al. (U.S. Patent No. 6,048,640) (hereafter Walters). As the limitation formerly recited in claim 21 is now included in independent claims 17, 28 and 53, this rejection has also been overcome.

In the Office Action, the Examiner also rejected claims 17, 26-28, 33, 35-38, 40-43, 45-53 and 56-59 under 35 U.S.C. 103(a) as being unpatentable over Walters in view of Bishay et al. (U.S. Patent No. 5,951,598) (hereafter Bishay). As the limitation formerly recited in claim 21 is now included in independent claims 17, 28 and 53, these rejections of independent claims 17, 28 and 53 have now been overcome.

In the Office Action, the Examiner rejected claims 17, 21 and 22 under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (U.S. Patent No. 5,462,157) (hereafter Freeman) in view of Jacobsson et al. (U.S. Patent No. 4,986,465) (hereafter Jacobsson). Applicants again note that claim 17 has now been amended to recite the features formerly recited in claim 21.

Applicants respectfully traverse the rejection of former claim 21 as being obvious over Freeman in view of Jacobsson.

In the Office Action, the Examiner stated that Freeman shows all of the claimed features except for a ring-shaped handle. However, the Examiner stated that Jacobson teaches a ring-shaped handle, and concluded that a person of ordinary skill in the art would have been motivated to incorporate the ring-shaped handle of Jacobson into the device of Freeman to arrive at Applicants' claimed invention because it is well known in the art of packing containers to use a ring shape so a person can insert a finger or thumb to grasp the handle.

Contrary to the Examiner's statements, however, Freeman does not teach all of the features of claims 17, 21 and 22 except for a ring shaped handle. In particular, Freeman lacks any suggestion of a pouch, but describes a structurally rigid sheet with a liner that is adhesively

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secured to the sheet. A structurally rigid sheet with a liner that is adhesively secured to the sheet is not the same as a pouch. Moreover, no reasonable interpretation of the term "pouch" would read on a structurally rigid sheet with a liner adhesively secured to the sheet, as taught by Freeman. Applicants noted this point in the previous response, but the Examiner has failed to respond to Applicants' arguments, or even address why the Examiner's interpretation of Freeman is appropriate.

Furthermore, contrary to the Examiner's conclusions, Jacobson lacks any teaching that would have led a person of ordinary skill in the art to modify the electrode package of Freeman to include a pouch with a ring-shaped handle that when pulled tears open the pouch. On the contrary, a person of ordinary skill in the art viewing Freeman would not have even looked to Jacobson for at least two reasons.

First, Jacobson is totally unrelated to medical devices or electrode packaging. Instead, Jacobson is concerned with packaging of consumer goods, and is specifically concerned with providing an opening that improves pouring properties of a container. Accordingly, a person of ordinary skill in the art would not have looked to Jacobson for guidance in the field of medical devices and electrode packaging.

Second, Freeman purports to address the issue of electrode package opening through the use of tabs that can be forced to break a heat seal and separate a sheet from a liner to open the package of Freeman. Thus, having identified a solution to electrode packaging consistent with the teaching of Freeman, a person of ordinary skill in the art would have had no reason to look elsewhere, much less look to unrelated consumer packaging techniques for improved liquid pouring properties, as taught by Jacobson.

In short, Applicants submit that the prior art lacks any motivation that would have led a person of ordinary skill in the art to even look to Jacobson. Further, even if a skilled person became aware of Jacobson, there would have been no reason to modify the tabs of Freeman into a ring-shaped handle, as Freeman purports to solve problems related to opening of electrode packages. Finally, Jacobson describes consumer packaging techniques for improved liquid pouring properties, and appears to have no applicability to electrode packaging in the medical device field.

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Applicants also respectfully note for the record that this is now the second time Applicants have identified these deficiencies in the Examiner's rejection of claim 21 as being unpatentable over Freeman in view of Jacobsson. In the latest Office Action, the Examiner failed to even acknowledge Applicants' arguments relating to the differences between Freeman and Jacobsson and claim 21, and also failed to acknowledge Applicants arguments relating to the lack of motivation to combine the teaching of these references. Unless the Examiner can identify a legally sufficient reason why a person of ordinary skill in the art would have been motivated to modify the electrode package of Freeman to include a pouch with a ring-shaped handle for consumer goods to improve liquid pouring properties, as taught by Jacobson, claim 17 (former claim 21) must be allowed.

For each of the reasons outlined above, allowance of claims 17, 28 and 53 is courteously solicited.

#### Claims 35 and 41

Independent claim 35 recites a device comprising a defibrillation electrode; a human figure printed on the defibrillation electrode; and an electrode symbol printed on the human figure, wherein the human figure is oriented on the defibrillation electrode at an angle relative to the defibrillation electrode, wherein the angle is non-zero such that when the defibrillation electrode is applied to a patient with the head of the patient and the head of the human figure in the same direction, the defibrillation electrode will be oriented on the patient at the angle, wherein the angle defines proper placement of the defibrillation electrode on the patient for defibrillation therapy. In this Amendment, Applicants have amended claim 35 to further clarify the human figure is oriented on the defibrillation electrode at an angle relative to the defibrillation electrode, wherein the angle is non-zero.

Independent claim 41 recites a method comprising printing a human figure on a defibrillation electrode; and printing an electrode symbol on the human figure on the defibrillation electrode, wherein the human figure is oriented on the defibrillation electrode at an angle relative to the defibrillation electrode, wherein the angle is non-zero such that when the defibrillation electrode is applied to a patient with the head of the patient and the head of the human figure in the same direction, the defibrillation electrode will be oriented on the patient at

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the angle, wherein the angle defines proper placement of the defibrillation electrode on the patient for defibrillation therapy. Like claim 35, claim 41 has been amended to further clarify the human figure is oriented on the defibrillation electrode at an angle relative to the defibrillation electrode, wherein the angle is non-zero.

In the Office Action, the Examiner rejected claim 35 under 35 U.S.C. §102(e) as being anticipated by Nova et al. (U.S. Patent Publication No. 2003/0114885) (hereafter Nova). The Examiner stated that the electrodes of Nova each show a human figure oriented on a defibrillation electrode at an angle, and cited FIG. 3 of Nova in support of the rejection.

Applicants believe that this rejection is without merit, particularly with respect to amended claim 35. While Nova shows electrodes printed with human figures, the orientation of the human figures on the electrodes of Nova are not oriented at angles that define proper placement of the defibrillation electrodes when the head of the patient and the head of the human figure are in the same direction. The current amendment should even further clarify this distinction insofar as the current claims now specify that the angle is a non-zero angle.

In Nova, the heads of the human figures printed on electrodes 22 would not be oriented in the same direction as that of the patient, when the electrodes are placed for defibrillation therapy. Put another way, if the human figures on electrodes 22 were positioned such that the heads of the human figures were oriented in the same direction as that of the patient, the electrodes would be misplaced for defibrillation therapy. Moreover, to the extent the figures on electrodes 22 could be construed as being formed at an angle when the heads of the figures are oriented in the same direction as that of the patient, in Nova, the angle would be zero degrees, in contrast to Applicants' claims which now require non-zero angles when the heads of the figures are oriented in the same direction as that of the patient.

This distinguishing feature of Applicants' claim 35 relative to the prior art can simplify the proper placement of electrodes, by orienting the human figure on the electrode in a manner that defines proper placement of the defibrillation electrode when the head of the figures is oriented in the same direction as the head of the patient. This is not shown or suggested in Nova, as the figures in Nova are printed the same on both electrode irrespective of desired electrode placement. Withdrawal of the rejection of claim 35 under 35 U.S.C. §102(e) as being anticipated by Nova is solicited.

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In the Office Action, the Examiner also rejected claims 17, 26-28, 33, 35-38, 40-43, 45-53 and 56-59 under 35 U.S.C. 103(a) as being unpatentable over Walters in view of Bishay; and rejected claims 23, 24, 25, 28, 32, 35, 39, 41, 43, 44, 53 and 54 under 35 U.S.C. 103(a) as being unpatentable over Walters in view of Bishay and further in view of Nova.

Applicants respectfully traverse these rejections with respect to claims 35 and 41 to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicants' claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention. In these rejections, the Examiner recognized that Walters fails to suggest instructive pictures on the electrodes, but stated that Bishay teaches the use of images on electrodes to assist an operator in determining placement of the electrodes.

Applicants respectfully traverse the rejections of claims 35 and 41 under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Bishay, particularly to the extent such rejections are deemed applicable to the amended claims. While Bishay shows electrodes printed with human figures, the orientation of the human figures on the electrodes of Bishay are not oriented at non-zero angles that define proper placement of the defibrillation electrodes when the head of the patient and the head of the human figure are in the same direction. In this sense, Bishay is very similar to Nova. As can be clearly seen in FIG. 1 of Bishay, the heads of figures on electrodes 12 and 12' would not be oriented in the same direction as that of the patient, when the electrodes are placed for defibrillation therapy.

Applicants believe that the current amendment further clarify this distinction between the pending claims and Walters and Bishay insofar as the current claims now specify that the angle is a non-zero angle. To the extent the printed figures in Bishay could be construed as being formed at an angle when the heads of the human figures on the electrodes are oriented in the same direction as the head of the patient, in Bishay, the angle would be zero degrees, in contrast to Applicants' claims which now require non-zero angles when the heads of the figures are oriented in the same direction as that of the patient. Withdrawal of the rejections of claim 35 and 41 under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Bishay is solicited.

In the Office Action the Examiner also rejected claims 35 and 41 under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Bishay and further in view of



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Nova. Applicants note that this rejection is inconsistent with the rejection of claims 35 and 41 under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Bishay. On one hand, the Examiner is stating that that Walters and Bishay disclose all of the features of claims 35 and 41, and on the other hand, the Examiner is stating that Walters and Bishay fail to suggest at least one feature of claims 35 and 41. In the previous response, Applicants specifically requested clarification on this inconsistency, but the Examiner has yet failed to address the inconsistency.

In any case, Applicants respectfully traverse the rejections of claims 35 and 41 under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Bishay and further in view of Nova, particularly to the extent such rejections are deemed applicable to the amended claims. As outlined above, neither Bishay nor Nova, nor any applied references suggests electrodes printed with human figures oriented at non-zero angles, wherein the non-zero angles define proper placement of the defibrillation electrodes for defibrillation therapy when the head of the patient and the head of the human figure are in the same direction.

While Bishay and Nova show electrodes printed with human figures, the orientation of the human figures on the electrodes of Bishay are not oriented at non-zero angles that define proper placement of the defibrillation electrodes when the head of the patient and the head of the human figure are in the same direction. To the extent the human figures of Bishay or Nova might be construed as being formed at an angle when the heads of the human figures on the electrodes are oriented in the same direction as the head of the patient, the angle would be zero degrees in Bishay and Nova, in contrast to Applicants' claims, which require non-zero angles. Withdrawal of the rejections of claim 35 and 41 under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Bishay and further in view of Nova is solicited.

In view of the comments above, Applicants believe that claims 35 and 41 are in condition for allowance.

#### Claim 47

In the Office Action, the Examiner also rejected claims 17, 26-28, 33, 35-38, 40-43, 45 53 and 56-59 under 35 U.S.C. 103(a) as being unpatentable over Walters in view of Bishay. Applicants respectfully traverse this rejection with respect to claim 47.



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Claim 47 recites a device comprising a right defibrillation electrode including a first instructive picture, and a left defibrillation electrode including a second instructive picture. As claimed, the first instructive picture includes a right electrode symbol on a first human figure, the first human figure oriented in a first direction relative to the right defibrillation electrode, and the second instructive picture includes a left electrode symbol on a second human figure, the second human figure oriented in a second direction relative to the left defibrillation electrode. In the previous response, Applicants amended claim 47 to specify that the first direction is different than the second direction.

While Bishay shows electrodes printed with human figures, the orientation of the human figures on the electrodes of Bishay are the same for both electrodes, and not different, as recited in claim 47. For at least this reason, the rejection of claim 47 under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Bishay should be withdrawn.

Applicants note that this is now the second time Applicants have advanced this argument with respect to claim 47. To date, the Examiner has failed to address Applicants' arguments or the deficiencies of the applied references with respect to claim 47. In Bishay, the orientation of the human figures on the electrodes are not different, as required by claim 47. For this reason, the rejection of claim 47 as being unpatentable over Walters in view of Bishay is improper. Neither reference discloses or suggests human figures printed on right and left electrodes at different orientations.

### CONCLUSION

Applicants believe that all claims in this application are in condition for allowance. Applicants respectfully request reconsideration and prompt allowance of all pending claims. With regard to the various dependent claims or features not specifically addressed herein, Applicants reserve further comment at this time. However, Applicants do not acquiesce to any of the Examiner's rejections or characterizations of the prior art, and reserve the right to present additional arguments. Please charge any additional fees or credit any overpayment to deposit

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account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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